Appendix D – Effectiveness evidence tables

Allison, 2007

Bibliographic Reference	Allison, Mandy A; Crane, Lori A; Beaty, Brenda L; Davidson, Arthur J; Melinkovich, Paul; Kempe, Allison; School-based health centers: improving access and quality of care for low-income adolescents.; Pediatrics; 2007; vol. 120 (no. 4); e887-94

Study details

Study type	Retrospective cohort study
Study location	USA
Study setting	School-based clinics and community clinics
Study dates	2002 to 2003
Sources of funding	National Research Service Award, Health Resources and Services Administration
Inclusion criteria	A specific age group: 14- to 17-year-olds seen at any Department of Health outpatient facility (school-based health clinic, community clinic, urgent care center, emergency department, or specialty clinic). Participants had to be registered at a Denver public school. Specified insurance status: Uninsured or insured by Medicaid or the State Children's Health Insurance Program because these adolescents were "less likely to seek care outside of the Department of Health system".
Exclusion criteria	Specified insurance status: Private or military health insurance Not enrolled at a state school
Intervention(s)	School-based health clinics (SBHCs). SBHCs were designed to provide primary care services for uninsured, underinsured, low-income, and minority children whose access to care is otherwise limited. SBHCs are usually staffed by health care professionals, such as nurses, nurse practitioners, physician assistants, behavioural health specialists, and physicians, who provide physical and mental health services with an emphasis on prevention. All of the students are encouraged to use the SBHC; however, parents must provide consent for their children to enrol to use the SBHC. Although the SBHCs billed students' insurance if possible, they did not require a co-payment or out-of-pocket payment from the student or family. The SBHCs provided preventive and primary health care services including immunisations, mental health services, referrals to specialty services, and access to after-hours telephone advice, urgent care, and emergency services in the DH system. They are designed to provide primary care for those students who do not have a primary care provider and to augment care for those who do. The SBHCs do provide pregnancy testing, diagnosis and treatment of sexually transmitted infections, and family planning and birth control counselling, but students are referred to DH community clinics for prenatal care and contraception management. The SBHCs are open during hours of school operation and are closed during school holidays.
Comparator	Cohort members who used a Department of Health community clinic at least once during the study period but did not use a school-based health clinic. The 9 Department of Health community clinics were open weekdays from 8:30 AM to 5:30

	PM and provided primary health care and preventive services, including contraception management, obstetric services, and access to after-hours services. Some of the community clinics also provided specialty services, including mental health care. Insured patients were often required to provide a co-payment, depending on the type of insurance, whereas uninsured patients paid out of pocket based on a sliding scale system. The SBHCs and community clinics used the same immunization schedule and followed the same Department of Health immunisation protocol.
Number of participants	1715
Duration of follow-up	Not applicable – this was a retrospective study. Adolescents needing a tetanus booster were identified, and receipt of a tetanus booster during the study period was compared between SBHC users and other users.
Loss to follow-up	Not applicable – this was a retrospective study.
Additional comments	The study included participants who either did not attend a Department of Health institution or only attended urgent/emergency department services. However, no tetanus vaccine uptake data was collected for these participants. The study also had data on influenza and HepB vaccination but this was excluded because these are not on the UK routine vaccination schedule for 11-18 year olds.

Study arms

School-based health centre users (N = 790)
Other users (used a community clinic at least once during the study but did not use a school-based health centre) (N = 925)

Characteristics

Arm-level characteristics

	School-based health centre users (N = 790)	**Other users (used a community clinic at least once during the study but did not use a school-based health centre) (N = 925)**
Age *(years)*		
Mean/SD	15.6 (1.1)	15.5 (1.2)
% Female *(%)*		
Nominal	61.4	66.4

Section	**Question**	**Answer**
1. Bias due to confounding	Risk of bias judgement for confounding	Low
2. Bias in selection of participants into the study	Risk of bias judgement for selection of participants into the study	Low

Section	Question	Answer
3. Bias in classification of interventions	Risk of bias judgement for classification of interventions	Low
4. Bias due to deviations from intended interventions	Risk of bias judgement for deviations from intended interventions	Serious *(Because SBHC users could use both SBHCs and community clinics, some of the SBHC users' immunisations occurred at community clinics rather than at an SBHC. Among SBHC users, 24.2% of tetanus immunisations occurred at a community clinic.)*
5. Bias due to missing data	Risk of bias judgement for missing data	Low
6. Bias in measurement of outcomes	Risk of bias judgement for measurement of outcomes	Serious *(There was no explanation as to how data was collected. It is possible that effort was required to collect data. Therefore, the effort expended to collect data may have been different depending on which arm the participants were in.)*
7. Bias in selection of the reported result	Risk of bias judgement for selection of the reported result	Low
Overall bias	Risk of bias judgement	Serious *(Issues with deviations from intended interventions and data collection.)*
	Directness	Directly applicable

Altinoluk-Davis, 2020

Bibliographic Reference	Altinoluk-Davis F; Gray S; Bray I; Measuring the effectiveness of catch-up MMR delivered by school nurses compared to signposting to general practice on improving MMR coverage.; Journal of public health (Oxford, England); vol. 42 (no. 2)

Study details

Study type	Retrospective cohort study
Study location	UK
Study setting	Schools
Study dates	2000 to 2001
Sources of funding	The study was undertaken as part of a Masters course – no funding was provided.
Inclusion criteria	A specific age group: All adolescents in year 9 (age 13-14 years) A specified area: Bath and North East Somerset, Berkshire, Buckinghamshire, Gloucestershire, Oxfordshire, Swindon and Wiltshire.
Exclusion criteria	None
Intervention(s)	MMR catch-up campaign by school nurses administering the vaccine to adolescents. No further information was provided.

Comparator	MMR catch-up campaign by school nurses signposting adolescents to general practice. No further information was provided.
Outcome measures	Vaccine uptake
Number of participants	27527
Duration of follow-up	Not applicable – this was a retrospective cohort study.
Loss to follow-up	None
Additional comments	MMR uptake data was collected at 3 different time points. For the evidence review, the latest time point was used because these results are summative. Uptake data was collected for 0, 1, 2, and >2 doses. 2 doses was used for the evidence review because this signifies dose course completion.

Study arms

MMR catch-up campaign by school nurses administering the vaccine to adolescents (N = 20936)
MMR catch-up campaign by school nurses signposting adolescents to general practice (reminder) (N = 6591)

Characteristics

Arm-level characteristics

	MMR catch-up campaign by school nurses administering the vaccine to adolescents (N = 20936)	**MMR catch-up campaign by school nurses signposting adolescents to general practice (reminder) (N = 6591)**
% Female *(%)*		
Nominal	50.3	49.5

Section	**Question**	**Answer**
1. Bias due to confounding	Risk of bias judgement for confounding	Low
2. Bias in selection of participants into the study	Risk of bias judgement for selection of participants into the study	Moderate *(MMR uptake at baseline was not quite equal for each arm. This is important given that participant numbers were high and the effect sizes between each arm were small. For example, the percentage of participants who had 0 doses of MMR at baseline was 11.6% for the vaccinations at school arm and 5.6% for the reminders arm. Given the large number of participants, this might suggest there were differences in uptake that were determined by where participants lived because the area where they lived determined which arm they would be in.)*
3. Bias in classification of interventions	Risk of bias judgement for classification of interventions	Low

Section	Question	Answer
4. Bias due to deviations from intended interventions	Risk of bias judgement for deviations from intended interventions	Low
5. Bias due to missing data	Risk of bias judgement for missing data	Low
6. Bias in measurement of outcomes	Risk of bias judgement for measurement of outcomes	No information
7. Bias in selection of the reported result	Risk of bias judgement for selection of the reported result	Low
Overall bias	Risk of bias judgement	Serious *(There was no description as to how uptake data was collected, stored and retrieved. There were baseline differences in uptake between the arms. Serious risk of bias because this is a retrospective cohort study. Therefore, it is prone to bias compared to randomised controlled trials.)*
	Directness	Directly applicable

Aoki, 2020

Bibliographic Reference	Aoki, T.; Fukuhara, S.; Associations of Types of Primary Care Facilities with Adult Vaccination and Cancer Screening in Japan; International journal for quality in health care : journal of the International Society for Quality in Health Care; 2020

Study details

Trial registration number and/or trial name	They used data collected from the primary care organizations reciprocal evaluation survey study (PROGRESS) 2018, which was conducted in a primary care practice-based research network (PBRN)
Study type	Retrospective cohort study
Study location	Japan
Study setting	Hospital and community primary care clinics
Study dates	2018
Sources of funding	Institute for Health Economics and Policy, Japan
Inclusion criteria	A specific age group: Participants aged 20 years or older. Pneumococcal vaccine eligibility age was 65 years of age or older. Received care from a specific organisation: Outpatients who normally received care a primary care facility who participated in the PROGRESS survey Participant matched inclusion criteria for vaccination
Exclusion criteria	None

Intervention(s)	Hospital primary care clinics. Small- and medium-sized hospitals with beds were run by two or more full-time physicians and other healthcare professionals and provided inpatient care in addition to outpatient and possibly home care. No further information was provided.
Comparator	Community primary care clinics. Community clinics were generally run by one full-time physician, nurses and medical assistants, and they provided outpatient and possibly home care. No further information was provided.
Outcome measures	Vaccine uptake
Number of participants	958
Duration of follow-up	Not applicable – this was a retrospective cohort study.
Loss to follow-up	Not applicable – this was a retrospective cohort study.
Additional comments	Data on influenza vaccine was also included in the study but was not included because this is beyond the scope of the protocol of this evidence review.

Study arms

Hospital primary care clinics (N = 337)
Community primary care clinics (N = 621)

Characteristics

Arm-level characteristics

	Hospital primary care clinics (N = 337)	Community primary care clinics (N = 621)
% Female *(%)*		
Nominal	45.1	44
Participants aged 50 years and over *(%)*		
Nominal	75	76

Section	Question	Answer
1. Bias due to confounding	Risk of bias judgement for confounding	Low
2. Bias in selection of participants into the study	Risk of bias judgement for selection of participants into the study	Low
3. Bias in classification of interventions	Risk of bias judgement for classification of interventions	Low
4. Bias due to deviations from intended interventions	Risk of bias judgement for deviations from intended interventions	Low
5. Bias due to missing data	Risk of bias judgement for missing data	Low

Section	Question	Answer
6. Bias in measurement of outcomes	Risk of bias judgement for measurement of outcomes	Serious *(Participants were asked by way of a survey if they had received a pneumococcal vaccination. Participants might not have remembered correctly or filled the form in correctly.)*
7. Bias in selection of the reported result	Risk of bias judgement for selection of the reported result	Low
Overall bias	Risk of bias judgement	Serious *(Uptake was self-reported by participants.)*
	Directness	Directly applicable

Beck, 1997

Bibliographic Reference	Beck A; Scott J; Williams P; Robertson B; Jackson D; Gade G; Cowan P; A randomized trial of group outpatient visits for chronically ill older HMO members: the Cooperative Health Care Clinic.; Journal of the American Geriatrics Society; 1997; vol. 45 (no. 5)

Study details

Study type	Randomised controlled trial (RCT)
Study location	USA
Study setting	Primary care health centres
Study dates	Not provided
Sources of funding	Garfield Memorial Fund and the Research and Development Fund of the Kaiser Foundation Health Plan of Colorado.
Inclusion criteria	65 years of age or older and had a chronic illness falling into one or more of four categories: heart disease, lung disease, joint disease, or diabetes. Patients were further selected based on relatively high health care utilization patterns within the preceding 12 months, defined as one or more outpatient visits per month and one or more calls to the nurse or physician every 2 months.
Exclusion criteria	None
Intervention(s)	Group visit patients were contacted by the study nurse and scheduled for their initial group visit. Physicians' schedules were modified to incorporate monthly group visits for the 12-month duration of the intervention. Scheduling for future group visits occurred at the first visit. At the first group visit, the health care team was introduced, and ground rules for the groups were established, including participants respecting each others' opinions, responsibility for asking questions, and the importance of keeping the group appointments. Patient concerns about specific health care issues were discussed at the initial visit in order to incorporate them into future discussion topics. A clinical psychologist from the mental health department attended the first three sessions of each group in order to facilitate the bonding of the groups. The general group visit format was as follows: A 15-minute warm up and socialization period, followed by a 30-minute presentation of a specific health-related topic as well as information on disease processes by the physician or one of the members of the interdisciplinary team that supported the Cooperative Health Care Clinic. Topics included medications and drug-related

	problems (presented by a clinical pharmacist), exercise (presented by a physical therapist), nutrition (presented by a dietician), alternate care (for example, skilled nursing facilities), home safety, advance directives, and use of emergency care services. Time was allowed for patient questions and interaction. A 15-minute break in which patients could socialize and refreshments were provided. During the break, the nurse took blood pressure readings, reviewed patients' medical records for immunization status, and determined any immediate care needs and other pertinent medical information. Where necessary, the nurse scheduled individual physician visits for the patient and also completed medical-related paper work requested by patients. The physician circulated, attending to individual concerns raised by the patients. Fifteen minutes were devoted to questions and answers, and another 15 minutes for planning for the next meeting. Thirty minutes were set aside at the end of the visits to allow for brief one-to-one visits with the physician, as necessary. In addition, all patients were given their own summarized medical record to keep and to bring to each visit for review and update by the nurse.
Comparator	No change in medical care occurred for usual care patients. Their healthcare utilization was assessed through data from administrative databases and chart review.
Outcome measures	Vaccine uptake
Number of participants	321
Duration of follow-up	4 months
Loss to follow-up	None
Additional comments	This study was downgraded because we had to infer the intervention from what was written: Monthly group health check with primary care physician and nurse. They reviewed the records, identified those who were not vaccinated and then booked them in for vaccination if needed.

Study arms

Monthly group health check with primary care physician and nurse. Vaccination records were reviewed and vaccination appointments were booked (inferred from what was written) (N = 160)
Usual care (N = 161)

Characteristics

Arm-level characteristics

	Monthly group health check with primary care physician and nurse. Vaccination records were reviewed and vaccination appointments were booked (inferred from what was written) (N = 160)	**Usual care (N = 161)**
Nominal	72	75

Section	Question	Answer
Domain 1: Bias arising from the randomisation process	Risk of bias judgement for the randomisation process	Low
Domain 2a: Risk of bias due to deviations from the intended interventions (effect of assignment to intervention)	Risk of bias for deviations from the intended interventions (effect of assignment to intervention)	Low
Domain 3. Bias due to missing outcome data	Risk-of-bias judgement for missing outcome data	Low
Domain 4. Bias in measurement of the outcome	Risk-of-bias judgement for measurement of the outcome	Some concerns *(There was no blinding and the method of measurement was a mixture of database and chart review.)*
Domain 5. Bias in selection of the reported result	Risk-of-bias judgement for selection of the reported result	Low
Overall bias and Directness	Risk of bias judgement	High *(Issues with defining what the intervention was and measurement of outcome.)*
Overall bias and Directness	Overall Directness	Directly applicable

Birkhead, 1995

Bibliographic Reference Birkhead, G.S.; LeBaron, C.W.; Parsons, P.; Grabau, J.C.; Barr-Gale, L.; Fuhrman, J.; Brooks, S.; Rosenthal, J.; Hadler, S.C.; Morse, D.L.; The immunization of children enrolled in the special supplemental food program for women, infants, and children (WIC): The impact of different strategies; Journal of the American Medical Association; 1995; vol. 274 (no. 4); 312-316

Study details

Study type	Cluster randomised controlled trial
Study location	USA
Study setting	Community
Study dates	1991
Sources of funding	Centers for Disease Control and Prevention
Inclusion criteria	A specific age group: Aged 12 to 59 months A specified area: Families registered at 6 clinics in New York City Participant matched inclusion criteria for vaccination: Measles vaccination
Exclusion criteria	None
Intervention(s)	In accordance with policy, at all study sites the parents and guardians of children eligible for measles immunisation were taught about the complications of measles disease and the importance of measles immunisation. Educational materials were provided in English and Spanish on measles and on immunizations in general. Staff also stressed the importance of immunisations with parents in required group

	educational sessions. The names and telephone numbers of local health care providers where immunisations could be obtained were given to all eligible clients. **Intervention 1:** Escort: Children were accompanied by staff to the paediatric clinic in the same facility for express lane immunisation. Parents were told that vouchers would be available immediately on return from the escort. If there were a temporary contraindication to immunization (for example, high fever), parents were told to return when the child was well enough to be escorted. Staff continued to offer escort at subsequent visits to children who were not successfully escorted at study regionals. Food vouchers were dispersed according to the normal schedule whether families accepted or declined escort. **Intervention 2:** Voucher Incentive: The family returned on a monthly, rather than the normal every-2-months schedule, to pick up food vouchers until the child was immunised. No clients were ever denied at least a 1-month supply of food vouchers.
Comparator	Referral: The vaccination assessment, education, and referral services mandated by policy were provided, but no additional interventions were offered. No further information on reminders was provided. In accordance with policy, at all study sites the parents and guardians of children eligible for measles immunisation were taught about the complications of measles disease and the importance of measles immunisation. Educational materials were provided in English and Spanish on measles and on immunizations in general. Staff also stressed the importance of immunisations with parents in required group educational sessions. The names and telephone numbers of local health care providers where immunisations could be obtained were given to all eligible clients.
Outcome measures	Vaccine uptake
Number of participants	836
Duration of follow-up	8 months
Loss to follow-up	None
Additional comments	This study took place just after a large measles outbreak from 1990 to 1991 at New York City. There was no ICC provided in this study or in another similar study. Therefore, we adjusted the data for clustering using an ICC of 0.05, which was the most common ICC in the education and reminders evidence review. This study features in the access, reminders, and infrastructure evidence reviews.

Study arms

Child was escorted to a nearby paediatric clinic for immunisation + vouchers (N = 377)
Family was offered vouchers for monthly visits until child was immunised (N = 178)
Family was referred for immunisation (N = 281)

Characteristics

Arm-level characteristics

	Child was escorted to a nearby paediatric clinic for immunisation + vouchers (N = 377)	Family was offered vouchers for monthly visits until child was immunised (N = 178)	Family was referred for immunisation (N = 281)
Mother's median age *(years)*			
Nominal	26	26	29

Section	Question	Answer
1a. Bias arising from the randomisation process	Risk of bias judgement for the randomisation process	Low *(Although no details were provided about the randomisation process, the baseline characteristics were fairly equal for all 3 arms considering that it was a randomisation of 6 clinics.)*
1b. Bias arising from the timing of identification and recruitment of individual participants in relation to timing of randomisation	Risk of bias judgement for the timing of identification and recruitment of individual participants in relation to timing of randomisation	Low
2. Bias due to deviations from intended interventions	Risk of bias judgement for deviations from intended interventions	Low
3. Bias due to missing outcome data	Risk of bias judgement for missing outcome data	Low
4. Bias in measurement of the outcome	Risk of bias judgement for measurement of the outcome	Some concerns *(It is possible that lack of blinding and effort required to collect data could have biased the results in the arms in an uneven way.)*
5. Bias in selection of the reported result	Risk of bias for selection of the reported result	Low
Overall bias and Directness	Risk of bias judgement	Some concerns *(Some concerns with data collection.)*
	Overall Directness	Partially applicable *(This study began within weeks or months of a major measles outbreak ending in New York City. This is not a normal situation for routine vaccines and it could have influenced uptake.)*

Bond, 1998

Bibliographic Reference	Bond, L M; Nolan, T M; Lester, R A; Home vaccination for children behind in their immunisation schedule: a randomised controlled trial.; The Medical journal of Australia; 1998; vol. 168 (no. 10); 487-90

Study details

Study type	Randomised controlled trial (RCT)
Study location	Australia

Study setting	Community
Study dates	1996
Sources of funding	National Health and Medical Research Council
Inclusion criteria	Overdue a vaccination 90 days late for their third diphtheria-tetanus-pertussis/poliomyelitis Haemophilus influenzae type B vaccination (DTP/OPV/Hib; 1st milestone), or 120 days late for their measles-mumps-rubella vaccination (MMR; 2nd milestone).
Exclusion criteria	None
Intervention(s)	A nurse administered vaccination in the child's home at a time convenient to the parents. Siblings were also vaccinated if they were due for vaccination. The nurse providing the vaccination had completed a standard Victorian Government Department of Human Services immunisation course. A resuscitation kit (including adrenalin) was taken on each home visit, and the cold chain was maintained by transporting vaccines in a temperature-monitored car refrigerator. Before vaccination, the nurse administered a pre-vaccination health checklist to confirm the child's medical history, as obtained during the initial telephone contact, and to assess the child's health on the day of vaccination. Vaccines that were due were verified from the parent-held Child Health Record. The child's temperature was taken if he or she was hot or appeared unwell (a temperature ~ 38.5°C preclude vaccination). Paracetamol was offered to all children before vaccination. The nurse remained with the family for more than 20 minutes after vaccination.
Comparator	Two months after the intervention period, and based on updated information from the Australian Childhood Immunisation Register, they sent letters to parents of control children for whom neither the Register nor local councils had recorded a third DTP/OPV/Hib or an MMR vaccination. They followed the letters with a telephone call to verify vaccination status and to offer, in this case, vaccination at the Royal Children's Hospital. Parents of control children were also informed of local vaccination services offered by the maternal and child health nurse or of the schedules of mobile vaccination vans provided by local councils.
Outcome measures	Vaccine uptake
Number of participants	169
Duration of follow-up	No follow-up period for the intervention group. There was a 2 month follow-up period for the control group after the intervention period.
Loss to follow-up	None
Additional comments	No baseline characteristics for the 2 separate arms were provided.

Study arms

Home vaccination by nurse (N = 81)
Reminder (N = 88)

Section	Question	Answer
Domain 1: Bias arising from the randomisation process	Risk of bias judgement for the randomisation process	Low
Domain 2a: Risk of bias due to deviations from the	Risk of bias for deviations from the intended	Low

Section	Question	Answer
intended interventions (effect of assignment to intervention)	interventions (effect of assignment to intervention)	
Domain 2b: Risk of bias due to deviations from the intended interventions (effect of adhering to intervention)	Risk of bias judgement for deviations from the intended interventions (effect of adhering to intervention)	Low
Domain 3. Bias due to missing outcome data	Risk-of-bias judgement for missing outcome data	Low
Domain 4. Bias in measurement of the outcome	Risk-of-bias judgement for measurement of the outcome	Some concerns *(There was no blinding and the method of collecting outcome data was not explained. It is possible that bias could have been introduced by the lack of blinding if data collection required effort.)*
Domain 5. Bias in selection of the reported result	Risk-of-bias judgement for selection of the reported result	Low
Overall bias and Directness	Risk of bias judgement	Some concerns
	Overall Directness	Directly applicable

Bourdet, 2003

Bibliographic Reference	Bourdet SV; Kelley M; Rublein J; Williams DM; Effect of a pharmacist-managed program of pneumococcal and influenza immunization on vaccination rates among adult inpatients.; American journal of health-system pharmacy: AJHP : official journal of the American Society of Health-System Pharmacists; 2003; vol. 60 (no. 17)

Study details

Study type	Prospective cohort study
Study location	USA
Study setting	Hospital
Study dates	2001
Sources of funding	Not provided
Inclusion criteria	A specific age group: People aged 65 years or over or had a different indication for pneumococcal vaccine, such as (aged over 18 years with): diabetes, pulmonary disease, cardiovascular disease, kidney failure or disease, alcoholism or liver disease, compromised immune system. People admitted into hospital
Exclusion criteria	None
Intervention(s)	All adults greater than 18 years of age who were admitted to the general medicine, pulmonary medicine, and infectious diseases services were included in the intervention group and were considered for immunization. A pharmacist assigned to the medical service identified new admissions from daily census reports and screened the patients for indications for influenza and pneumococcal immunization according to the guidelines of the Advisory Committee

	on Immunization Practices. Pharmacists' participation in the vaccination program was voluntary. Initial information was retrieved from the inpatient medical chart and online medical record. Interviews were conducted by the pharmacist for patients with indications for immunisation to determine possible contraindications, to determine vaccination status, and to provide education. During the interview, patients were provided with vaccine information sheets published by the CDC. Because of difficulty in obtaining documentation of prior immunisations, vaccination status was determined by patient recall alone. For patients unsure of their vaccination status, immunization with influenza or pneumococcal vaccine was recommended in accordance with ACIP guidelines. For patients at risk of complications from intramuscular injections (e.g., anticoagulation, thrombocytopenia), the decision to immunize was discussed with the physician, and subsequent vaccination occurred under a physician order rather than a standing order. Vaccination standing orders were completed by the pharmacist for patients who had indications for vaccination, who had no contraindications, and who were agreeable to vaccination. A short form noting the pharmacist's intervention, including the vaccine ordered or the reason for not ordering a vaccine, was completed and placed in the patient's chart. Patients receiving vaccines during hospitalisation were given a wallet card upon discharge with documentation of the vaccines administered and the dates of vaccination.
Comparator	All patients admitted to the renal and gastrointestinal medicine, cardiology, and family medicine services were included in the control group. Control patients were not actively targeted by pharmacists for immunisation but were immunised if this was ordered by the health care provider during usual care. This study involves opportunistic vaccination and therefore involves identification of individuals suitable for vaccination, like a study in evidence review A.
Outcome measures	Vaccine uptake
Number of participants	1050. In the intervention group, there were 442 participants. However, only 214 of these were aged 65 years and over. In the control group, there were 608 participants. However, only 310 of these were aged 65 years and over.
Duration of follow-up	Follow-up data was collected at discharge from hospital.
Loss to follow-up	None
Additional comments	No relevant baseline characteristics were provided for each arm. This study included data for influenza vaccinations that were not used because influenza vaccinations are not part of this evidence review.

Study arms

Opportunistic vaccinations at a hospital (N = 442)
No opportunistic vaccinations at a hospital (N = 608)

Section	Question	Answer
1. Bias due to confounding	Risk of bias judgement for confounding	Low
2. Bias in selection of participants into the study	Risk of bias judgement for selection of participants into the study	Serious *(The recruitment locations were not equal for each arm: Participants in the intervention arm were on general medicine, pulmonary medicine, and infectious diseases wards. Participants in the control arm were on renal and gastrointestinal medicine, cardiology, and family medicine services. Indications for pneumococcal vaccination include the diseases listed in the inclusion criteria.)*
3. Bias in classification of interventions	Risk of bias judgement for classification of interventions	Low
4. Bias due to deviations from intended interventions	Risk of bias judgement for deviations from intended interventions	Low
5. Bias due to missing data	Risk of bias judgement for missing data	Low
6. Bias in measurement of outcomes	Risk of bias judgement for measurement of outcomes	Serious *(There was no blinding and details as to how data was collected was not provided. Therefore, data collection could have been biased if it required effort.)*
7. Bias in selection of the reported result	Risk of bias judgement for selection of the reported result	Low
Overall bias	Risk of bias judgement	Serious *(Issues with patient allocation and data collection.)*
	Directness	Partially Applicable *(Approximately 50% of participants in each arm were below the age of 65 years and were being vaccinated for indications other than age.)*

Conway, 1999

Bibliographic Reference	Conway SP; Opportunistic immunisation in hospital.; Archives of disease in childhood; 1999; vol. 81 (no. 5)

Study details

Study type	Uncontrolled before-and-after studies
Study location	UK
Study setting	Hospital
Study dates	Not provided
Sources of funding	Not provided

Inclusion criteria	A specific age group: 1000 consecutive pre-school children admitted onto a paediatric ward.
Exclusion criteria	None
Intervention(s)	The carers of preschool age children admitted to a paediatric ward were asked by the attending doctor about the immunisation status of their child. This was checked against the child health record book if available, or by telephone contact with the health authority computer database. The latter became routine work for the ward clerk. Where there was a conflict of information, the official record was taken as accurate unless cogent explanations were given for the discrepancy. The ward doctor was instructed to discuss immunisation with the family of any under immunised child and to offer appropriate immunisation on the ward before discharge. Consultants and middle grade staff were asked to emphasise the proactive nature of this policy on ward rounds. When available, reasons for carers refusing catch up immunisation were noted.
Comparator	Vaccination uptake on admission.
Outcome measures	Vaccine uptake
Number of participants	1000
Duration of follow-up	Not mentioned
Loss to follow-up	None
Additional comments	The vaccines that were assessed and offered were not mentioned. Baseline characteristics were not provided. This study involves opportunistic vaccination and therefore involves identification of individuals suitable for vaccination, like an evidence review A study.

Study arms

Pre-existing vaccination levels (before) (N = 1000)
Opportunistic parental education by a doctor and offer of a vaccination (after) (N = 1000)

Section	Question	Answer
Random sequence generation	Was the allocation sequence adequately generated?	NA
Allocation concealment	Was the allocation adequately concealed?	Unclear *(Blinding was not mentioned)*
Baseline outcome measurements	Were baseline outcome measurements similar?	NA
Baseline characteristics	Were baseline characteristics similar?	NA
Incomplete outcome data	Were incomplete outcome data adequately addressed?	NA

Section	Question	Answer
Knowledge of the allocated interventions	Was knowledge of the allocated interventions adequately prevented during the study?	NA
Protection against contamination	Was the study adequately protected against contamination?	Yes
Selective outcome reporting	Was the study free from selective outcome reporting?	Yes
Other risks of bias	Was the study free from other risks of bias?	No *(There is no mention of how vaccine uptake was recorded. There was no mention of blinding.)*
Overall judgements of risk of bias and directness	Overall risk of bias	High *(Issues with measuring outcomes)*
Overall judgements of risk of bias and directness	Overall directness	Partially applicable *(Relevant vaccines were general for age but were not provided in the methods section.)*

Dalby, 2000

Bibliographic Reference	Dalby, Dawn M; Sellors, John W; Fraser, Fred D; Fraser, Catherine; et, al; Effect of preventive home visits by a nurse on the outcomes of frail elderly people in the community: A randomized controlled trial: CMAJ; Canadian Medical Association. Journal; 2000; vol. 162 (no. 4); 497-500

Study details

Study type	Randomised controlled trial (RCT)
Study location	Canada
Study setting	Community (home visits versus control)
Study dates	Not provided
Sources of funding	Ontario Ministry of Health
Inclusion criteria	A specific age group: People 70 years of age and over A specified area: On the roster of 2 physicians affiliated with a health service organisation in Stoney Creek, Ontario (primary care). Specified health condition(s): Functional impairment or admission to hospital or bereavement in the last 6 months.
Exclusion criteria	Living in a nursing home Involved in another research study Had previously been visited by the nurse in their home Other Had participated in the pre-test of the survey.

Intervention(s)	The visiting nurse used the “functional consequences theory” of gerontologic nursing. The goals are to minimise the negative effects of age-related changes and risk-factors and to promote positive functional consequences. The nurse reviewed each person’s medical record and completed a comprehensive assessment addressing physical, cognitive, emotional and social function, medication use, and the safety and suitability of the home environment. A care plan was developed together with the primary care physician, the patient, the family, caregivers and other health professionals. Follow-up visits and phone calls were conducted as needed over the course of the 14-month trial to provide vaccinations, monitor, promote health and provide psychological support. The nurse served as a case manager by integrating community services and agencies, such as Home Care, into the participants’ care plan.
Comparator	Usual care
Outcome measures	Vaccine uptake
Number of participants	142
Duration of follow-up	14 months
Loss to follow-up	14 participants withdrew from the study in the intervention arm (12 of these were lost to follow-up) and 15 participants withdrew from the study in the usual care arm (10 of these were lost to follow-up).
Additional comments	This study included data for influenza that was not relevant to this evidence review.

Study arms

Visiting nurse (N = 73)
Control (N = 69)

Characteristics

Arm-level characteristics

	Visiting nurse (N = 73)	**Control (N = 69)**
Age *(years)*		
Mean/SD	79.1 (5.8)	78.1 (5.3)
% Female *(%)*		
Nominal	71.2	62.3

Section	**Question**	**Answer**
Domain 1: Bias arising from the randomisation process	Risk of bias judgement for the randomisation process	Low
Domain 2a: Risk of bias due to deviations from the intended interventions (effect of assignment to intervention)	Risk of bias for deviations from the intended interventions (effect of assignment to intervention)	Low

Section	Question	Answer
Domain 3. Bias due to missing outcome data	Risk-of-bias judgement for missing outcome data	Low
Domain 4. Bias in measurement of the outcome	Risk-of-bias judgement for measurement of the outcome	Low
Domain 5. Bias in selection of the reported result	Risk-of-bias judgement for selection of the reported result	Some concerns *(There was no blinding of the people who did the data collection. The data collection required effort and therefore could have been prone to bias.)*
Overall bias and Directness	Risk of bias judgement	Some concerns *(Some concerns with data collection.)*
	Overall Directness	Directly applicable

Daniels, 2007

Bibliographic Reference	Daniels, Nicholas A; Juarbe, Teresa; Moreno-John, Gina; Perez-Stable, Eliseo J; Effectiveness of adult vaccination programs in faith-based organizations.; Ethnicity & disease; 2007; vol. 17 (no. 1suppl1); 15-22

Study details

Study type	Cluster randomised controlled trial
Study location	USA
Study setting	Churches
Study dates	Not provided
Sources of funding	Centre for Aging in Diverse Communities, National Institute on Aging, the National Institute of Nursing Research, and the National Center on Minority Health and Health Disparities.
Inclusion criteria	A specific age group Aged 65 years and over or having clinical indication for vaccination (diabetes, chronic lung disease, cardiovascular disease, chronic kidney disease) People who attend the churches included in the study
Exclusion criteria	None
Intervention(s)	The intervention happened in churches. During the adult vaccine education session component of the intervention, participants learned about influenza and pneumonia vaccines in group discussions that lasted <1 hour. Study participants at sites that were randomised for on-site vaccination were also offered the vaccines, which were administered by the investigators with medical training. All participants were assessed at baseline and during 3- to 6-month follow-up telephone interviews to assess receipt of vaccination.
Comparator	The comparator happened in churches. Those who become part of the comparison group received informational pamphlets, church-based education on adult vaccinations, and physician reminders that participants should see their physicians for vaccinations and watched a slide presentation on benefits and side effects of influenza and pneumococcal vaccinations. All participants were assessed at baseline and during 3- to 6-month follow-up telephone interviews to assess receipt of vaccination.

Outcome measures	Vaccine uptake
Number of participants	186
Duration of follow-up	6 months
Loss to follow-up	None
Additional comments	Only the data for pneumococcal vaccination uptake was extracted because influenza vaccination is covered in a different guideline. Adjusted odds ratio for clustering was not provided. The data was not adjusted for clustering because the number of churches in each arm was not provided. In the study, they provide per protocol analysis results (they did not include participants who had already had a pneumonia vaccine). In the data synthesis of this evidence review, intention to treat results have been calculated.

Study arms

Vaccination at church (N = 113)
Reminders (N = 73)

Arm-level characteristics

	Vaccination at church (N = 113)	**Reminders (N = 73)**
Age *(years)*		
Mean/SD	64 (14)	67 (13)
% Female *(%)*		
Nominal	78	70

Section	**Question**	**Answer**
1a. Bias arising from the randomisation process	Risk of bias judgement for the randomisation process	Some concerns *(The method of randomisation was not provided. However, the baseline characteristics of the participants is roughly equal for both arms.)*
1b. Bias arising from the timing of identification and recruitment of individual participants in relation to timing of randomisation	Risk of bias judgement for the timing of identification and recruitment of individual participants in relation to timing of randomisation	Low
2. Bias due to deviations from intended interventions (If your aim is to assess the effect of assignment to intervention, answer the following questions).	Risk of bias judgement for deviations from intended interventions	High *(The methods of education were not the same for both arms.)*
3. Bias due to missing outcome data	Risk of bias judgement for missing outcome data	Low

Section	Question	Answer
4. Bias in measurement of the outcome	Risk of bias judgement for measurement of the outcome	High *(The investigators telephoned the participants to ask them about their vaccination status. This method is less reliable than documentation done at the time of vaccination or use of a vaccine registry. Furthermore, neither the participants nor the investigators were blinded, which could have introduced bias because they knew which arms they were in.)*
5. Bias in selection of the reported result	Risk of bias for selection of the reported result	Low
Overall bias and Directness	Risk of bias judgement	High
	Overall Directness	Directly applicable

El-Mohandes, 2003

Bibliographic Reference	El-Mohandes, Ayman A E; Katz, Kathy S; El-Khorazaty, M Nabil; McNeely-Johnson, Doris; Sharps, Phyllis W; Jarrett, Marian H; Rose, Allison; White, Davene M; Young, Michal; Grylack, Larry; Murray, Kennan D B; Katta, Pragathi S; Burroughs, Melissa; Atiyeh, Ghassan; Wingrove, Barbara K; Herman, Allen A; The effect of a parenting education program on the use of preventive pediatric health care services among low-income, minority mothers: a randomized, controlled study.; Pediatrics; 2003; vol. 111 (no. 6pt1); 1324-32

Study details

Trial registration number and/or trial name	Pride in Parenting
Study type	Randomised controlled trial (RCT)
Study location	USA
Study setting	
Study dates	April 1995 – April 1997
Sources of funding	NICHD, NIH Office of Research on Minority Health
Inclusion criteria	Women who had inadequate or no prenatal care Less than 5 prenatal visits or care initiated in 3rd trimester At least 18 years of age, English-speakers, no history of psychiatric illness, not incarcerated and not planning on placing the baby for adoption
Exclusion criteria	Baby delivered before 34-weeks' gestation, weighed less than 1500 g, or had congenital abnormalities

Intervention(s)	Yearlong intervention including home visits, parent-infant developmental play groups, parent support groups, and monthly support calls from the Pride in Parenting family resource specialist. Home visits, usually weekly, were from a lay home visitor who participated in a 9-week training programme. Home visitors followed a standard curriculum including health and child care topics relevant to the child's age as well as providing health and development information and facilitated use of community health and social services resources. At 5 months of age, home visits alternated with group sessions which included the play groups and parent support groups. Lesson plans for each play group and support group ensured consistency across sites.
Comparator	Standard social services support – Monthly phone calls from a Pride in Parenting family resource specialist who provided referrals to health care, social support services and other community resources
Relevant outcome measures	Vaccine uptake Completion of the immunisation schedule
Duration of follow-up	1 year
Loss to follow-up	4 months – 27.6% 8 months – 34.6% 12 months – 41.6% Numbers not reported for individual arms
Additional comments	Study also reports individual vaccine uptake at 2, 4, 6, 9 and 12 months. Only completion of immunisation schedule at 12 months is included in the analysis for this review because this is the latest time point and is therefore a more summative result.

Study arms

Home visits and parental support (N = 146) Home visits, developmental play groups, parent support groups and monthly support calls
Control (N = 140) Standard social services support

Risk of bias

Section	Question	Answer
Domain 1: Bias arising from the randomisation process	Risk of bias judgement for the randomisation process	Some concerns *(Limited information about the randomisation process)*
Domain 2: Risk of bias due to deviations from the intended interventions	Risk of bias for deviations from the intended interventions	Low

Section	Question	Answer
Domain 3. Bias due to missing outcome data	Risk-of-bias judgement for missing outcome data	High *(Only 58.4% of participants remained in the trial at 12 months. No information about the proportions missing from each group)*
Domain 4. Bias in measurement of the outcome	Risk-of-bias judgement for measurement of the outcome	Low
Domain 5. Bias in selection of the reported result	Risk-of-bias judgement for selection of the reported result	Low
Overall bias and Directness	Risk of bias judgement	High *(Limited information about randomisation methods. High number of dropouts by 12 months – no information about how this differed between arms.)*
	Overall Directness	Directly applicable

Federico, 2010

Bibliographic Reference	Federico, Steven G; Abrams, Lisa; Everhart, Rachel M; Melinkovich, Paul; Hambidge, Simon J; Addressing adolescent immunization disparities: a retrospective analysis of school-based health center immunization delivery.; American journal of public health; 2010; vol. 100 (no. 9); 1630-4

Study details

Study type	Retrospective cohort study
Study location	USA
Study setting	School-based health centres and community health centres.
Study dates	2006 to 2008
Sources of funding	Not provided
Inclusion criteria	A specific age group Males and females aged 12 to 18 years A specified area Adolescents who had received care within the Denver Health system.
Exclusion criteria	None
Intervention(s)	Vaccination at school-based health centres. No further details are provided.
Comparator	Vaccination at community health centres. No further details are provided.
Outcome measures	Vaccine uptake
Number of participants	There were 17349 children and adolescents aged 12 to 18 years who received care in the Denver Health system during the study interval: 8144 (47%) at CHCs, 6668 (38%) at SBHCs, and 2537 (15%) at both. After those who used both sites were classified on the basis of which site they visited the most, there were 9132 (53%) CHC users and 8217 (47%) SBHC users.

Duration of follow-up	This was a snapshot of uptake of participants aged 12 to 18 years as they visited health centres from 1/8/2006 to 31/7/2008.
Loss to follow-up	None
Additional comments	Only the HPV and meningococcal results were relevant to the protocol but the data for meningococcal vaccine (MCV4) was not provided in an extractable format. The Tdap, varicella, HepA, and HepB vaccines are not routinely given to 11-18 year olds in the UK. Baseline characteristics were not provided.

Study arms

School-based health centre vaccination (N = 8217)
Community health centre (N = 9132)

Section	Question	Answer
1. Bias due to confounding	Risk of bias judgement for confounding	Low
2. Bias in selection of participants into the study	Risk of bias judgement for selection of participants into the study	Serious *(No baseline characteristics were provided. Therefore, we do not know whether each arm is a like-for-like comparison. For example, similar ages and genders for both arms.)*
3. Bias in classification of interventions	Risk of bias judgement for classification of interventions	Serious *(Descriptions of the interventions were not provided.)*
4. Bias due to deviations from intended interventions	Risk of bias judgement for deviations from intended interventions	Serious *(2537 (15%) of participants received both interventions. From study: 'For patients who used both clinical settings, we decided a priori to classify them into either the SBHC group or the CHC group, depending on which clinic they used the most.)*
5. Bias due to missing data	Risk of bias judgement for missing data	Low
6. Bias in measurement of outcomes	Risk of bias judgement for measurement of outcomes	Serious *(The method of data collection was not provided.)*
7. Bias in selection of the reported result	Risk of bias judgement for selection of the reported result	Low
Overall bias	Risk of bias judgement	High
	Directness	Directly applicable

Ginson, 2000

Bibliographic Reference	Ginson, S.H.; Malmberg, C.; French, D.J.; Impact on vaccination rates of a pharmacist-initiated influenza and pneumococcal vaccination program; Canadian Journal of Hospital Pharmacy; 2000; vol. 53 (no. 4); 270-275

Study details

Study type	Cluster randomised controlled trial
Study location	Canada
Study setting	Hospital
Study dates	1997
Sources of funding	Not provided
Inclusion criteria	People admitted into hospital Participant matched inclusion criteria for vaccination For pneumonia and/or influenza vaccination: Age >65 years, chronic cardiac or pulmonary disorder, chronic condition, liver cirrhosis, alcohol misuse, immunosuppression due to disease.
Exclusion criteria	Participant had exclusion criteria for vaccine(s) Known anaphylactic hypersensitivity to eggs (influenza vaccine only), acute febrile illness, terminal illness or palliative care, resident of nursing home or chronic care facility, previous receipt of both current influenza vaccine and a pneumococcal vaccine, inability to give informed consent.
Intervention(s)	Patient-focused education and a standing order for vaccination (automatic vaccination). The pharmacist reviewed the benefits and potential side effects of vaccination with each patient, using a pamphlet to highlight relevant information about the vaccines. Material in the pamphlet was based on empirically derived determinants of vaccination behaviour, both cognitive (fear of contracting influenza from the vaccine) and behavioural (transportation and visit time). Patients were informed that both vaccines were available in the hospital and were asked to give written consent to be vaccinated. Eligibility and consent to be vaccinated in the patient's chart, and a conditional order for the appropriate vaccine or vaccines was written by the pharmacist. The order required a physician's signature before the vaccine could be administered. A record of in-hospital vaccination was forwarded to the patient and his or her family physician.
Comparator	No information was provided. Presumably no intervention and usual care.
Outcome measures	Vaccine uptake
Number of participants	102
Duration of follow-up	Vaccination status after the intervention phase of the study.
Loss to follow-up	None
Additional comments	This is a cluster RCT because it was the physicians who were randomised to the arms. The patients they were managing were allocated to arms depending on who their physician was. The data was adjusted for clustering: there were 16 clusters in the intervention arm and 25 clusters in the control arm. No ICC was provided by a cRCT in this evidence review so an ICC of 0.05 was used because this was the most common ICC in the education and reminders evidence review.

Study arms

Vaccine education and offer by hospital pharmacist (N = 50)
Control (N = 52)

Arm-level characteristics

	Vaccine education and offer by hospital pharmacist (N = 50)	Control (N = 52)
Age *(years)*		
Mean/SD	65.6 (17.5)	70.2 (14)
% Female *(%)*		
Nominal	66	67

Section	Question	Answer
1a. Bias arising from the randomisation process	Risk of bias judgement for the randomisation process	Low
1b. Bias arising from the timing of identification and recruitment of individual participants in relation to timing of randomisation	Risk of bias judgement for the timing of identification and recruitment of individual participants in relation to timing of randomisation	Low
2. Bias due to deviations from intended interventions (If your aim is to assess the effect of assignment to intervention, answer the following questions).	Risk of bias judgement for deviations from intended interventions	Low
3. Bias due to missing outcome data	Risk of bias judgement for missing outcome data	Low
4. Bias in measurement of the outcome	Risk of bias judgement for measurement of the outcome	Some concerns *(There was no blinding of the clinical staff. This could have affected the staff's behaviour in the control arm.)*
5. Bias in selection of the reported result	Risk of bias for selection of the reported result	Low
Overall bias and Directness	Risk of bias judgement	Some concerns *(Lack of staff blinding could have affected the advice and prescribing behaviour of clinicians in the control arm.)*
	Overall Directness	Partially applicable *(The intention to treat data included participants who were due to have a pneumonia vaccine or an influenza vaccine. The exclusion criteria included participants who were residents of a nursing home or chronic care facility.)*

Johnson, 1993

Bibliographic Reference	Johnson Z; Howell F; Molloy B; Community mothers' programme: randomised controlled trial of non-professional intervention in parenting.; BMJ (Clinical research ed.); 1993; vol. 306 (no. 6890)

Study details

Other publications associated with this study included in review	Johnson 2000
Trial registration number and/or trial name	Community Mothers Programme
Study type	Randomised controlled trial (RCT)
Study location	Ireland
Study setting	Communities in Dublin
Study dates	6 months in 1989 (exact dates not specified)
Sources of funding	Bernard van Leer Foundation, The Hague
Inclusion criteria	First time mothers who delivered over six months in 1989 and lived in a defined deprived area
Exclusion criteria	None reported
Intervention(s)	Community Mothers Programme – aimed at using experienced volunteer mothers in disadvantaged areas to give support to first time parents using the child development programme. Potential community mothers were identified by the local public health nurse and interviewed by a regional family development nurse to assess suitability. Community mothers were given 4 weeks of training and were given opportunities to meet other community mothers to explore ways of delivering the programme. After training, each community mother worked under the guidance of a family development nurse, who served as a resource person, confidante, and monitor. Each community mother aimed at supporting five to 15 first time parents.
Comparator	Control (usual care). Both groups also received the standard support from their own local public health nurse, which consisted of visits at birth and six weeks and at other times as required. Both groups received invitations to attend for primary immunisations and a development assessment.
Relevant outcome measures	Vaccine uptake Number of children who had received all three shots of their primary immunisations by their first birthday
Number of participants	262
Duration of follow-up	Until the child's first birthday

Loss to follow-up	Intervention: 12, Control: 16
Additional comments	Study also reports individual data on diphtheria-tetanus-pertussis, but this review only analyses number of children who had completed the immunisation schedule by their first birthday

Study arms

Community Mothers Programme (N = 127)
Experienced volunteer mothers trained by public health nurse and visit first-time parents once per month to provide education. Standard support from local public health nurse

Control (N = 105)
Standard support from local public health nurse

Characteristics

Arm-level characteristics

	Community Mothers Programme (N = 127)	**Control (N = 105)**
Mother's age *(years)*		
Mean/SD	24.1 (4.4)	23.1 (3.7)
% Female		
Nominal	51	51

Risk of bias

Section	**Question**	**Answer**
Domain 1: Bias arising from the randomisation process	Risk of bias judgement for the randomisation process	Low *(Most baseline characteristics were similar, with the exception of parents employment. However, the authors controlled for this in the analysis, finding no significant effects on the results)*
Domain 2: Risk of bias due to deviations from the intended interventions	Risk of bias for deviations from the intended interventions	Some concerns *(No information about analysis methods to estimate the effects of assignment to intervention)*
Domain 3. Bias due to missing outcome data	Risk-of-bias judgement for missing outcome data	Low
Domain 4. Bias in measurement of the outcome	Risk-of-bias judgement for measurement of the outcome	Some concerns *(Vaccination rates were assessed by questionnaires completed by the parents which could be subjective if the parents were aware of the intervention received. The study states that this was cross-checked with other*

Section	Question	Answer
		sources of information but no further information on what this was)
Domain 5. Bias in selection of the reported result	Risk-of-bias judgement for selection of the reported result	Low
Overall bias and Directness	Risk of bias judgement	Some concerns *(No information about analysis methods to estimate the effect of assignment to intervention. Vaccine uptake was based on parent reports which could be a subjective outcome)*
	Overall Directness	Directly applicable

Johnson, 2000

Bibliographic Reference	Johnson Z; Molloy B; Scallan E; Fitzpatrick P; Rooney B; Keegan T; Byrne P; Community Mothers Programme–seven year follow-up of a randomized controlled trial of non-professional intervention in parenting.; Journal of public health medicine; 2000; vol. 22 (no. 3)

Study details

Secondary publication of another included study- see primary study for details	Johnson 1993 – 7-year follow-up of the 1993 study
Study type	Randomised controlled trial (RCT)
Relevant outcome measures	Vaccine uptake MMR
Number of participants	Original study children: 721 7 years later, 38 intervention and 39 control parents were located (32.8% of the original sample). They all agreed to participate in a follow-up. At this point, vaccine uptake (Hib and polio) for subsequent children was measured.
Duration of follow-up	7 years after the 1993 study
Loss to follow-up	None

Additional comments	This data was presented separately to Johnson 1993 to prevent double-counting. This is a 7-year follow-up with fewer participants.

Study arms

Community mother (N = 127)

Inclusion criteria	First time mothers

Control (N = 105)

Relevant outcome measures	Vaccine uptake

Characteristics

Arm-level characteristics

	Community mother (N = 127)	Control (N = 105)
% Female *(%)* (infant)		
Nominal	51	51
Single parent family *(%)*		
Nominal	52	62
Percentage in local authority housing *(%)*		
Nominal	56	64

Risk of bias

Section	Question	Answer
Domain 1: Bias arising from the randomisation process	Risk of bias judgement for the randomisation process	Low *(Participant characteristics similar for those traced for this study. However, there were some differences in parent employment rates in the 1993 study but this was controlled for and not found to affect the results.)*
Domain 2: Risk of bias due to deviations from the intended interventions	Risk of bias judgement for deviations from the intended interventions	Low

Section	Question	Answer
Domain 3. Bias due to missing outcome data	Risk-of-bias judgement for missing outcome data	Some concerns *(Only 32.8% of the original sample could be contacted to take part in the study)*
Domain 4. Bias in measurement of the outcome	Risk-of-bias judgement for measurement of the outcome	Some concerns *(Unclear how vaccine uptake information was obtained. If it was by parent reports then this outcome could be subjective)*
Domain 5. Bias in selection of the reported result	Risk-of-bias judgement for selection of the reported result	Some concerns *(Limited information on analysis methods)*
Overall bias and Directness	Risk of bias judgement	High *(A small proportion of the original sample (33%) could be contacted to take part in the follow-up study. Unclear how vaccine uptake data was obtained and limited information about analysis methods)*
	Overall Directness	Directly applicable

Kaul, 2019

Bibliographic Reference	Kaul, S.; Do, T.Q.N.; Hsu, E.; Schmeler, K.M.; Montealegre, J.R.; Rodriguez, A.M.; School-based human papillomavirus vaccination program for increasing vaccine uptake in an underserved area in Texas; Papillomavirus Research; 2019; vol. 8; 100189

Study details

Study type	Prospective cohort study
Study location	USA
Study setting	Schools
Study dates	2016 to 2018
Sources of funding	Cancer Prevention Research Institute of Texas.
Inclusion criteria	A specific age group 6th-, 7th-, and 8th-grade students (aged 11 to 14 years in the USA school system)
Exclusion criteria	None
Intervention(s)	They piloted their school-based HPV vaccination event at the intervention school. Vaccination events were held in the nurse's office or conference room. The events were scheduled for the HPV vaccine series to be initiated and completed during the school year (i.e., back-to-school events, progress report nights, and schedule preview events). Five HPV vaccination events were held between August 2017 and April 2018. Prior to these events, consent forms were sent home with students by school staff. At each vaccination event, 2 tables were set up – one with educational materials and another for the vendor that was contracted by the project to administer on-site vaccinations at the school (ProCare Health Services). The vendor had the parents sign in and complete the consent form for the vaccinations as well as register their child with ImmTrac, the Texas Immunization Registry, to track and document vaccinations. For educational purposes, parents were required to be

	present when the first dose of the vaccine was administered. It usually took less than 10 min for students to get vaccinated. The HPV vaccine was bundled with other recommended vaccines (e.g., flu, Meningococcal, Meningitis B, Tetanus, Diphtheria [TD], or Tetanus, Diphtheria, and Pertussis [TDAP] and Hepatitis A vaccines). The vendor's medical assistants administered the vaccines. Before vaccination, the vendor screened the children for their health insurance coverage (ie, private health insurance, Medicaid, Children's Health Insurance Program [CHIP], Texas Vaccination Program) to bill for vaccine administration. Although uninsured children receive vaccines free of charge through the VFC program, there is a vaccine administration charge. According to county estimates, ~20% of the parents cannot afford to pay the $10 admin fee. Their program covered the administrative fee if the child had no payer. If a child missed a dose, efforts were made to catch up through the supporting clinics and subsequent vaccination events. Their vaccine vendor also provided the student vaccination data, which supplemented the school immunisation records. The vendor collected student vaccination data (vaccine, dose number) during the vaccine administration. All records were refreshed quarterly by the vendor and school. There was also an educational component that was present in both arms of the study: Their educational program was uniformly delivered to stakeholders in the surrounding community. All 3 schools were exposed to the same community-based education program starting in 2016. The educational presentations occurred at school-based (e.g., health fairs, vaccination days, back-to-school nights, Parent-Teacher Association [PTA], school board, and monthly nurse meetings) and community events (e.g., health department events with Starr, Hidalgo, and Cameron; regional conferences; training sessions/workshops). The PowerPoint presentation included details on HPV (e.g., what is HPV, how does it spread, incidence and burden of HPV, HPV vaccine guidelines etc.) and their funded project (e.g., their program's focus on increasing HPV vaccination rates and its significance, importance, components, and goals). The 30-min educational presentations were delivered by the study investigators (1 gynaecologist and 1 oncologist) with time allotted for questions from the audience. A paediatrician was also present to answer questions. They emphasised the benefits of vaccination, the recommended age, and the importance of provider recommendations and distributed existing educational materials in English and Spanish from the Centres for Disease Control and Prevention (CDC). These educational materials were also delivered to paediatric and family health clinics located within a 15-mile radius. When requested at school-based events, parents/guardians received one-on-one education by their study personnel. For school-based events, the researchers posted educational flyers and fact sheets on the importance of getting students vaccinated against HPV. They also used social media (eg, Facebook), local radio stations, and newspapers to provide a description of their program and advertise events.
Comparator	Only the educational components were provided. The school-based HPV vaccination event was not part of the control.
Outcome measures	Vaccine uptake
Number of participants	2307
Duration of follow-up	The latest date at which data was collected (4/25/2018) has been used because this is the largest data set and is the summative data.
Loss to follow-up	None

Study arms

School-based vaccination (N = 885)

Control (N = 1422)

Arm-level characteristics

	School-based vaccination (N = 885)	Control (N = 1422)
Age *(years)*		
Mean/SD	12 (0.9)	12 (0.9)
% Female *(%)*		
Nominal	52	47

Section	Question	Answer
1. Bias due to confounding	Risk of bias judgement for confounding	Low
2. Bias in selection of participants into the study	Risk of bias judgement for selection of participants into the study	Low
3. Bias in classification of interventions	Risk of bias judgement for classification of interventions	Low
4. Bias due to deviations from intended interventions	Risk of bias judgement for deviations from intended interventions	Low
5. Bias due to missing data	Risk of bias judgement for missing data	Low
6. Bias in measurement of outcomes	Risk of bias judgement for measurement of outcomes	Serious *(There was no blinding and the method of collecting outcome data was not explained. It is possible that bias could have been introduced by the lack of blinding if data collection required effort.)*
7. Bias in selection of the reported result	Risk of bias judgement for selection of the reported result	Low
Overall bias	Risk of bias judgement	Moderate
	Directness	Directly applicable

Kitzman, 1997

Bibliographic Reference Kitzman, H.; Olds, D.L.; Henderson Jr., C.R.; Hanks, C.; Cole, R.; Tatelbaum, R.; McConnochie, K.M.; Sidora, K.; Luckey, D.W.; Shaver, D.; Engelhardt, K.; James, D.; Barnard, K.; Effect of prenatal and infancy home visitation by nurses on pregnancy outcomes, childhood injuries, and repeated childbearing: A randomized controlled trial; Journal of the American Medical Association; 1997; vol. 278 (no. 8); 644-652

Study details

Study type	Randomised controlled trial (RCT)
Study location	USA
Study setting	Nurse visits in the community by nurses from an obstetric clinic.
Study dates	June 1990 – August 1991
Sources of funding	National Institute of Nursing Research, the Bureau of Maternal and Child Health, the Administration for Children and Families, the Office of the Assistant Secretary for Planning and Evaluation, the National Center for Child Abuse and Neglect, Robert Wood Johnson Foundation, the Carnegie Corporation of New York, the Pew Charitable Trusts, and the William T. Grant Foundation.
Inclusion criteria	Pregnant women These women were followed-up until their children were 2 years old. Women less than 29 weeks pregnant were recruited if they had no previous live births, no specific chronic illnesses thought to contribute to fetal growth retardation or preterm delivery (for example, chronic hypertensive disorders requiring medical treatment, severe cardiac disease, large uterine fibroids) Sociodemographic risk conditions At least 2 of the following sociodemographic risk conditions: unmarried, less than 12 years of education, and unemployed.
Exclusion criteria	None
Intervention(s)	Two arms of this study were not included in this review because vaccine uptake was not reported. Arms 2 (control for the nurse visit arm) and 4 (nurse visit arm) were relevant to this review. Women in the nurse visit arm were provided free transportation and developmental screening and referral services for the child at 6, 12 and 24 months of age. Women also had intensive nurse home-visitation services during pregnancy, 1 postpartum visit in the hospital before discharge, and 1 postpartum visit in the home. They continued to be visited by nurses until the child's 2nd birthday.
Comparator	Free transportation for scheduled prenatal care plus developmental screening and referral services for the child at 6,12, and 24 months of age.
Relevant outcome measures	Vaccine uptake MMR and DtaP – vaccines up to date at 2 years of age
Number of participants	743
Duration of follow-up	24 months from birth
Loss to follow-up	None
Additional comments	Four arm study but only 2 arms reported vaccine uptake

Study arms

Nurse visits (N = 228)
Free transport for prenatal care, developmental screening and referral services. Nurse home visits from during the pregnancy until the child was 2 years of age

Control (N = 515)
Free transport for prenatal care, developmental screening and referral services

Characteristics

Arm-level characteristics

	Nurse visits (N = 228)	Control (N = 515)
Women who were married *(%)*		
Nominal	1	2
Years of education *(years)*		
Mean/SD	10.1 (2)	10.3 (1.9)
Head of household employed *(%)*		
Nominal	50	57
Mother's age *(years)*		
Mean/SD	18.1 (3.2)	18.1 (3.3)

Risk of bias

Section	Question	Answer
Domain 1: Bias arising from the randomisation process	Risk of bias judgement for the randomisation process	High *(No information about the randomisation process or allocation concealment)*
Domain 2: Risk of bias due to deviations from the intended interventions	Risk of bias judgement for deviations from the intended interventions	Low
Domain 3. Bias due to missing outcome data	Risk-of-bias judgement for missing outcome data	Some concerns *(Unclear whether data was available for all participants)*
Domain 4. Bias in measurement of the outcome	Risk-of-bias judgement for measurement of the outcome	Low
Domain 5. Bias in selection of the reported result	Risk-of-bias judgement for selection of the reported result	Low

Section	Question	Answer
Overall bias and Directness	Risk of bias judgement	Some concerns *(No information about the randomisation process or allocation concealment. No information about whether data was available for all participants)*
	Overall Directness	Directly applicable

Koniak-Griffin, 2003

Bibliographic Reference	Koniak-Griffin D; Verzemnieks IL; Anderson NL; Brecht ML; Lesser J; Kim S; Turner-Pluta C; Nurse visitation for adolescent mothers: two-year infant health and maternal outcomes.; Nursing research; 2003; vol. 52 (no. 2)

Study details

Trial registration number and/or trial name	Early Intervention Program
Study type	Randomised controlled trial (RCT)
Study location	USA
Study setting	Community Health Services Division of the County Health Department in San Bernardino, California
Study dates	Not reported
Sources of funding	National Institute of Nursing Research, the Office of Research on Women's Health, NINR
Inclusion criteria	First time mothers 14-19 years of age At 26 weeks gestation or less Planning to keep the baby
Exclusion criteria	Dependent on narcotic or injection drugs Had a documented serious medical or obstetric problem
Intervention(s)	One nurse providing continuous care to her assigned adolescent from pregnancy until 1 year postpartum. Four "preparation-for-motherhood" classes focused on behaviours to promote health during pregnancy, parent-child communication, and the transition to motherhood. Following childbirth, PHNs demonstrated selected components of the Neonatal Behavioural Assessment Scale and provided videotape instruction and feedback to improve parenting behaviours. Teaching and counselling

	were provided for health promotion, life planning, building problem-solving skills, and securing resources such as social support, child care, and health services). The programme was designed to include up to 17 home visits: 2 prenatal, and 15 postpartum (1.5 to 2 hours each).
Comparator	Traditional Public Health Nursing Care – services comparable to those often available in county health departments lacking special funding for adolescent programs. Included 1 prenatal home visit after the participant's entry into the study, and a 2nd visit during the 3rd trimester. Visits focused on (a) assessment and counselling related to prenatal healthcare, (b) self-care, (c) preparation for childbirth, (d) education planning, and € well-baby care, including immunizations. Within 6 weeks postpartum, the PHN made an additional home visit to provide the mother with general information about child care, postpartum recovery, maternal and infant nutrition, home safety, community resources, and family planning.
Relevant outcome measures	Vaccine uptake Infants adequately immunised (4 or more doses of diphtheria-tetanus-pertussis vaccine, 3 or more doses of poliovirus vaccine, and 1 or more doses of measles-containing vaccine were received by 24 months of age)
Number of participants	101
Duration of follow-up	2 years
Loss to follow-up	Not reported

Study arms

Early Intervention Program (N = 56) Public Health nurse home visits – providing care to the adolescent from pregnancy to 1 year postpartum
Traditional Public Health Nursing Care (N = 45) Standard public health care

Characteristics

Arm-level characteristics

	Early Intervention Program (N = 56)	**Traditional Public Health Nursing Care (N = 45)**
Mother's age *(years)*		
Mean/SD	16.75 (1.24)	16.84 (1)
Gestational age at enrolment *(Weeks)*		
Mean/SD	20.67 (5.92)	20.25 (5.12)

Risk of bias

Section	Question	Answer
Domain 1: Bias arising from the randomisation process	Risk of bias judgement for the randomisation process	Some concerns *(Limited information about randomisation methods and allocation concealment)*
Domain 2: Risk of bias due to deviations from the intended interventions (effect of assignment to intervention)	Risk of bias for deviations from the intended interventions (effect of assignment to intervention)	Low
Domain 3. Bias due to missing outcome data	Risk-of-bias judgement for missing outcome data	Low
Domain 4. Bias in measurement of the outcome	Risk-of-bias judgement for measurement of the outcome	Low
Domain 5. Bias in selection of the reported result	Risk-of-bias judgement for selection of the reported result	Low
Overall bias and Directness	Risk of bias judgement	Low
	Overall Directness	Directly applicable

Li, 1991

Bibliographic Reference	Li, J; Taylor, B; Comparison of immunisation rates in general practice and child health clinics.; BMJ (Clinical research ed.); 1991; vol. 303 (no. 6809); 1035-8

Study details

Study type	Retrospective cohort study
Study location	UK
Study setting	General practices and child health clinics
Study dates	1990 to 1991
Sources of funding	North East Thames Regional Health Authority
Inclusion criteria	A specific age group: Children aged 10 to 12 months
Exclusion criteria	Individuals who had incomplete data Children whose data on vaccination location were not available in the child health system.
Intervention(s)	Community child health clinics. No further details of the intervention were provided.
Comparator	General practices. No further details of the intervention were provided.
Outcome measures	Vaccine uptake
Number of participants	3616
Duration of follow-up	Not applicable – this was a retrospective cohort study.

Loss to follow-up	Not applicable – this was a retrospective cohort study.
Additional comments	Data for uptake of the third pertussis dose was used rather than data for uptake of the first pertussis dose because the former is a later and therefore more summative result. The only baseline characteristic provided was number of children registered by type of district, which is included below.

Study arms

Community child health clinics (N = 1114)
General practice (N = 2502)

Characteristics

Arm-level characteristics

	Community child health clinics (N = 1114)	General practice (N = 2502)
Rural/suburban *(%)*		
Nominal	10.2	89.8
Inner city *(%)*		
Nominal	61.6	38.4

Section	Question	Answer
1. Bias due to confounding	Risk of bias judgement for confounding	Low
2. Bias in selection of participants into the study	Risk of bias judgement for selection of participants into the study	Low
3. Bias in classification of interventions	Risk of bias judgement for classification of interventions	Low
4. Bias due to deviations from intended interventions	Risk of bias judgement for deviations from intended interventions	Low
5. Bias due to missing data	Risk of bias judgement for missing data	Low
6. Bias in measurement of outcomes	Risk of bias judgement for measurement of outcomes	Low
7. Bias in selection of the reported result	Risk of bias judgement for selection of the reported result	Low
Overall bias	Risk of bias judgement	Moderate *(Moderate risk of bias because it is a retrospective cohort study and therefore has more innate risk of bias compared to a randomised controlled trial.)*
	Directness	Directly applicable

Norr, 2003

Bibliographic Reference	Norr KF; Crittenden KS; Lehrer EL; Reyes O; Boyd CB; Nacion KW; Watanabe K; Maternal and infant outcomes at one year for a nurse-health advocate home visiting program serving African Americans and Mexican Americans.; Public health nursing (Boston, Mass.); 2003; vol. 20 (no. 3)

Study details

Trial registration number and/or trial name	REACH-Futures
Study type	Randomised controlled trial (RCT)
Study location	USA
Study setting	2 prenatal clinics of the University of Illinois at Chicago Medical Center
Study dates	Not reported
Sources of funding	The Agency for Health Care and Policy Research, the National Center for Nursing Research, the Dean's Fund, College of Nursing, University of Illinois at Chicago.
Inclusion criteria	Pregnant women Low-income, inner-city women who lived in community areas with high infant mortality Medicaid or state supplemental health insurance eligibility (income under 150% of poverty), address in a neighbourhood with high infant mortality, medically and obstetrically low risk, and no evidence of current drug use
Exclusion criteria	None reported
Intervention(s)	REACH-Futures. A community worker–nurse team combined the health knowledge of the nurse and the advocates' understanding of the community. All program educational materials were available in English and Spanish. Each team of 1 nurse and 2 health advocates followed 150 families. Families were contacted once a month and more often if necessary. The advocates conducted the first home visit within 2 weeks of discharge. At each visit, the advocate discussed the mother's concerns and problems as well as developmental changes, appropriate parenting, and positive discipline strategies. The advocate also assessed home safety and reviewed infant health. The nurse accompanied the advocate at 1, 6, and 12 months to conduct infant health and development screening. The advocate also helped the mother schedule visits at the health facility. Home visits did not replace regular well-child visits. After 2 months, a phone call could replace visits, with home follow-up if problems were identified.
Comparator	Routine well-child visits at the clinic or provider of the family's choice (standard care).
Relevant outcome measures	Vaccine uptake Immunisations complete at 12 months (based on medical record and mother's reports)
Number of participants	588

Duration of follow-up	12 months
Loss to follow-up	19% (figures not reported per arm)

Study arms

REACH-Futures (N = 258) Home visits and phone contact to discuss mother's questions with nurse and community advocate (182 African Americans, 76 Mexican Americans)
Control (N = 219) Routine well-child visits at the clinic or provider of their choice (standard care) (141 African Americans, 78 Mexican Americans)

Risk of bias

Section	Question	Answer
Domain 1: Bias arising from the randomisation process	Risk of bias judgement for the randomisation process	Some concerns *(Limited information about randomisation and allocation concealment)*
Domain 2: Risk of bias due to deviations from the intended interventions (effect of assignment to intervention)	Risk of bias for deviations from the intended interventions (effect of assignment to intervention)	Some concerns *(No information about analysis used to estimate the effect of assignment to intervention)*
Domain 3. Bias due to missing outcome data	Risk-of-bias judgement for missing outcome data	Some concerns *(No information about missing data)*
Domain 4. Bias in measurement of the outcome	Risk-of-bias judgement for measurement of the outcome	Low
Domain 5. Bias in selection of the reported result	Risk-of-bias judgement for selection of the reported result	Some concerns *(Limited information about analysis methods)*
Overall bias and Directness	Risk of bias judgement	Some concerns *(Limited information about randomisation and analysis methods. No information about missing data)*
	Overall Directness	Directly applicable

Pearson, 2005

Bibliographic Reference	Pearson, E.; Lang, E.; Colacone, A.; Farooki, N.; Afilalo, M.; Successful implementation of a combined pneumococcal and influenza vaccination program in a Canadian emergency department; Canadian Journal of Emergency Medicine; 2005; vol. 7 (no. 6); 371-377

Study details

Study type	Uncontrolled before-and-after studies
Study location	Canada

Study setting	Emergency department
Study dates	2001
Sources of funding	Programme le Ministere de la Sante et des Services sociaux, Regies 117egionals et Fronds de recherche en sante du Quebec, Brownstein Emergency Department, Armand Afilo, Family Emergency Department.
Inclusion criteria	A specific age group: Aged 65 years and over Specified health condition(s): Chronic disease: cardiac disease, pulmonary disease, renal disease, diabetes, immunosuppression, active cancer, HIV, spleen dysfunction, liver disease/chronic alcoholism.
Exclusion criteria	Participant had exclusion criteria for vaccine(s): Contraindication. Other: Interviewed in the emergency department during a previous visit Unable to communicate (in French or English) Specific medical conditions: Dementia, delirium Unable to sign a consent form. Non-resident of the country where the study took place
Intervention(s)	Opportunistic vaccination at an emergency department. All patients who visited the emergency department between 8am and 4pm during weekdays were screened for pneumonia vaccination eligibility (based on age and chronic disease). A research assistant approached all patients determined to be vaccine eligible. Unvaccinated patients who did not have a clear plan for vaccination elsewhere were offered vaccination in the emergency department. If the patient agreed, a vaccination order sheet was presented to the emergency physician to sign. Once ordered, the study nurse administered the pneumococcal vaccination.
Comparator	Of the 174 (out of 460) who had already been vaccinated, 52% had been vaccinated by a family physician, 20% had been vaccinated at a community health clinic, 6% had been vaccinated during chronic care at a hospital, and 21% had been vaccinated at an ‘other’ location.
Outcome measures	Vaccine uptake
Number of participants	460
Duration of follow-up	Data was collected after the visit to the emergency department.
Loss to follow-up	None
Additional comments	The study collected data for influenza vaccination. However, this data was not used in this review because influenza vaccination is not included in this evidence review. No baseline characteristics were collected by the study authors. This study involves opportunistic vaccination and therefore involves identification of individuals suitable for vaccination like in evidence review A study.

Study arms

Opportunistic vaccination at the emergency department (N = 460)

Section	Question	Answer
Random sequence generation	Was the allocation sequence adequately generated?	NA *(The study included all relevant participants during the recruitment time window.)*
Allocation concealment	Was the allocation adequately concealed?	NA *(The study included all relevant participants during the recruitment time window.)*
Baseline outcome measurements	Were baseline outcome measurements similar?	Unclear *(Baseline characteristics of those already vaccinated and those who were vaccinated in the emergency department were not collected.)*
Baseline characteristics	Were baseline characteristics similar?	Unclear *(This data was not collected)*
Incomplete outcome data	Were incomplete outcome data adequately addressed?	NA *(There was no incomplete outcome data)*
Knowledge of the allocated interventions	Was knowledge of the allocated interventions adequately prevented during the study?	NA *(It is unlikely that knowledge of the intervention would have affected participant behavior before their visit to the emergency department.)*
Protection against contamination	Was the study adequately protected against contamination?	Yes
Selective outcome reporting	Was the study free from selective outcome reporting?	Yes
Other risks of bias	Was the study free from other risks of bias?	No *(The method of data collection was not explained. This could have introduced bias because there was no blinding.)*
Overall judgements of risk of bias and directness	Overall risk of bias	High risk of bias *(Because baseline characteristics were not provided, it is difficult to say how comparable the before and after data are. No explanation of how data was collected and no blinding.)*
	Overall directness	Partially applicable *(The study included people aged 65 years and over as well as people with chronic medical conditions (attending an emergency department). The investigators do not say what proportion were aged 65 years and over.)*

Rodewald, 1996

Bibliographic Reference	Rodewald LE; Szilagyi PG; Humiston SG; Raubertas RF; Wassilak S; Roghmann KJ; Hall CB; Effect of emergency department immunizations on immunization rates and subsequent primary care visits.; Archives of pediatrics & adolescent medicine; 1996; vol. 150 (no. 12)

Study details

Study type	Randomised controlled trial (RCT)
Study location	USA

Study setting	An emergency department and 54 primary care practices in Monroe county, New York.
Study dates	1990 to 1991
Sources of funding	Centres for Disease Control and Prevention
Inclusion criteria	Children of a specific age Aged 6 to 36 months. Participants attended an emergency department
Exclusion criteria	None reported
Intervention(s)	When children attended an emergency department, they were randomised into a primary care reminder arm, emergency department vaccination arm or control groups. The emergency department vaccination arm: Parents of children who were not likely to be up to date with their vaccinations were offered vaccines that likely had not been previously administered and vaccination was not contraindicated. The reminder arm: No intervention in the emergency department. Less than a week later, the child's GP was sent a letter. If there was a chance that they might not be up to date with vaccinations, this was flagged up.
Comparator	No intervention with regards to vaccines.
Relevant outcome measures	Vaccine uptake The outcome was percentage / number of children up to date with their vaccinations. The study mentions diphtheria, tetanus, pertussis, polio, and Hib.
Number of participants	1835
Duration of follow-up	1 month
Loss to follow-up	none
Additional comments	The comparison of reminders vs control is included in the reminders evidence review C. This study involves opportunistic vaccination and therefore involves identification of individuals suitable for vaccination, like an evidence review A study.

Study arms

Primary care reminders (N = 610)
No reminders but offers of vaccinations in the emergency department (N = 611)
Control group: no reminders and no offers of vaccinations in the emergency department (N = 614)

Characteristics

Arm-level characteristics

	Primary care reminders (N = 610)	**No reminders but offers of vaccinations in the emergency department (N = 611)**	**Control group: no reminders and no offers of vaccinations in the emergency department (N = 614)**
Age *(Months)*			
Nominal	18.2	17.5	18

	Primary care reminders (N = 610)	No reminders but offers of vaccinations in the emergency department (N = 611)	Control group: no reminders and no offers of vaccinations in the emergency department (N = 614)
Sex: Female *(%)*			
Nominal	41	45	42

Section	Question	Answer
Domain 1: Bias arising from the randomisation process	Risk of bias judgement for the randomisation process	Low
Domain 2a: Risk of bias due to deviations from the intended interventions (effect of assignment to intervention)	Risk of bias for deviations from the intended interventions (effect of assignment to intervention)	Low
Domain 3. Bias due to missing outcome data	Risk-of-bias judgement for missing outcome data	Low
Domain 4. Bias in measurement of the outcome	Risk-of-bias judgement for measurement of the outcome	Some concerns *(Blinding was not mentioned. The investigators do not mention how the data for uptake was collected. Therefore, it is difficult to assess bias for data collection.)*
Domain 5. Bias in selection of the reported result	Risk-of-bias judgement for selection of the reported result	Low
Overall bias and Directness	Risk of bias judgement	Some concerns
	Overall Directness	Directly applicable

Stubbs, 2014

Bibliographic Reference	Stubbs, Brenda W; Panozzo, Catherine A; Moss, Jennifer L; Reiter, Paul L; Whitesell, Dianne H; Brewer, Noel T; Evaluation of an intervention providing HPV vaccine in schools.; American journal of health behavior; 2014; vol. 38 (no. 1); 92-102

Study details

Study type	Prospective cohort study This study involved clustering by way of schools
Study location	USA
Study setting	Schools
Study dates	2009 to 2010
Sources of funding	Guilford County Health Department
Inclusion criteria	A specific age group: Adolescent girls who were eligible for HPV vaccination and who were attending a participating school

Intervention(s)	The intervention was the same as the comparator arm except that adolescents in the intervention arm had a clinic at their school, but adolescents in the comparison arm did not – adolescents and parents had to travel to a school with a clinic. The core intervention team consisted of a project manager, clerical support staff, and a health educator, all of whom were employees of the Guilford County Department of Public Health. The core team assigned school health nurses to staff the clinics and held in-service training sessions for the nurses. The core team devised the information and consent packet for girls to take home to their parents. The packets contained a cover letter approved and signed by the Guilford County health director and Guilford County Schools' superintendent, the HPV and HPV vaccine fact sheet, the HPV vaccination consent form, the HPV vaccination waiver, clinic schedules, a statement that the vaccination clinics would incur no out-of-pocket expense, and an unstamped postcard survey (as described above) for parents declining vaccination. The packets were written at the eighth-grade reading level, and Spanish translations appeared on the back of all materials. The intervention plan was to send the packets home with every girl 2 weeks prior to the first vaccination clinics to allow enough time for the parents to read the packets and make a decision. Parents deciding to vaccinate their daughters at a school-located clinic brought signed consent forms from the packet to the first clinic; vaccinations provided during subsequent second and third dose clinics did not require additional consent. The core team also provided education and outreach. As described above, education was promoted largely by the earlier campaign, "Don't Wait… Educate!" In addition, during the vaccination intervention, a web campaign appeared on the Guilford County Department of Public Health website that provided continuing education and outreach to parents, and the health educator provided educational HPV presentations upon request. Parents also were reminded about the vaccination clinics through ConnectEd, an automated calling service, and the media relations manager promoted the school-located clinics through local media outlets. The clinics had to take place during non-instructional hours. Parents had to be present for all of their daughters' vaccinations, even if the parents signed a consent form. All principals of the host schools (6/6, or 100%) agreed to distribute HPV vaccine information and consent packets directly to the students. The information and consent packets took 2 months to create and receive approval from the local school system senior staff, local health director, and county attorney. Just prior to packet distribution, national media carried a negative story about the safety and potential side effects of the HPV vaccine. The officials who approved the packets asked the investigators to revise them to include a second, separate consent form that parents had to sign acknowledging the possibility of HPV vaccine side effects, including death. Due to concerns that the delayed packet distribution may have contributed to a low number of girls attending the first round of clinics offered in October, the investigators invited girls to receive their first dose of HPV vaccine at any of the clinics already planned in December 2009, and they added 3 second-dose clinics in February 2010 and 3 third-dose clinics in June 2010.
Comparator	The comparator was the same as the intervention except that the adolescents and parents had to travel to a school in the same USA county that had a clinic. Most principals of the satellite schools (15/16, or 94%) agreed to distribute HPV vaccine information and consent packets directly to the students.
Outcome measures	Vaccine uptake

Number of participants	7916
Duration of follow-up	The follow-up period was not provided.
Loss to follow-up	None
Additional comments	Baseline characteristics were not provided for both arms of the study.

Study arms

Schools with clinics (N = 1781) 6 schools had these clinics
Schools without clinics but were nearby a school that had a clinic (a "satellite school") (N = 6135) 14 schools were "satellite schools"

Section	Question	Answer
1. Bias due to confounding	Risk of bias judgement for confounding	Low
2. Bias in selection of participants into the study	Risk of bias judgement for selection of participants into the study	Moderate *(The investigators did not explain how they allocated schools to the clinic or satellite arms.)*
3. Bias in classification of interventions	Risk of bias judgement for classification of interventions	Low
4. Bias due to deviations from intended interventions	Risk of bias judgement for deviations from intended interventions	Low
5. Bias due to missing data	Risk of bias judgement for missing data	Low
6. Bias in measurement of outcomes	Risk of bias judgement for measurement of outcomes	Serious *(The method of data collection is not explained and the duration of follow-up is not provided. For example they did say whether data collection was blinded. The duration of follow-up could have varied depending on the school.)*
7. Bias in selection of the reported result	Risk of bias judgement for selection of the reported result	Moderate *(The investigators collected more data for each arm than just participants who received one dose of HPV or more. For example, they do not provide the data for completion of all 3 doses for each arm separately.)*
Overall bias	Risk of bias judgement	Serious *(There are issues with allocating schools to arms, data collection and selection of the reported result.)*

Section	Question	Answer
	Directness	Directly applicable

Szilagyi, 1997

Bibliographic Reference	Szilagyi PG; Rodewald LE; Humiston SG; Fierman AH; Cunningham S; Gracia D; Birkhead GS; Effect of 2 urban emergency department immunization programs on childhood immunization rates.; Archives of pediatrics & adolescent medicine; 1997; vol. 151 (no. 10)

Study details

Study type	Uncontrolled before-and-after studies
Study location	USA
Study setting	Emergency departments
Study dates	1992 to 1994
Sources of funding	New York State Department of Health, and Strong Children's Research Center.
Inclusion criteria	Pre-school age children (0 to 6.9 years) visiting emergency departments.
Exclusion criteria	None
Intervention(s)	Nurses were hired and trained to work in emergency departments to identify pre-school age children and offer immunizations. The vaccinations offered were: diphtheria, tetanus, pertussis, polio, MMR, Hib, HepB.
Comparator	Vaccine uptake at the start of the visit.
Outcome measures	Vaccine uptake
Number of participants	1301
Duration of follow-up	1 day
Loss to follow-up	None
Additional comments	We used the up-to-date vaccine uptake data at day 1 after the visit to the emergency department. This is because this result provides more accurate ED uptake data compared to the uptake data at 6 months, which would be contaminated by external factors. There were no relevant baseline characteristics. The before (control) data was calculated by us as follows: In the Manhattan group, 106 were vaccinated and 471 were not vaccinated. Of those vaccinated, 20% were already up to date with their vaccinations (20% of 106 = 21 participants). Of those not vaccinated, 74% were already up to date with their vaccinations (74% of 471 = 349). In the Bronx group, 129 were vaccinated and 595 were not vaccinated. Of those vaccinated, 20% were already up to date with their vaccinations (20% of 129 = 26 participants). Of those not vaccinated, 72% were already up to date with their vaccinations (72% of 595 = 428 participants). Therefore, altogether (21+349+26+428=) 824 were vaccinated prior to visiting the emergency departments.

	The number of participants who visited the emergency departments who were not up to date and left up to date was: For Manhattan: 76% vaccinated at day 1 – 20% already vaccinated of 106 participants who were vaccinated in the ED = 60. For Bronx: 70% vaccinated at day 1 – 20% of 129 who were vaccinated in the ED = 65. Therefore, altogether 125 participants were made newly up to date. 125+824 = 949 participants who were up to date in total after the emergency department visit. This study involves opportunistic vaccination and therefore involves identification of individuals suitable for vaccination, like an evidence review A study.

Study arms

After: opportunistic vaccination in emergency departments (N = 1301)
Before: control (N = 1301)

Section	Question	Answer
Random sequence generation	Was the allocation sequence adequately generated?	No
Allocation concealment	Was the allocation adequately concealed?	No
Baseline outcome measurements	Were baseline outcome measurements similar?	NA
Baseline characteristics	Were baseline characteristics similar?	NA
Incomplete outcome data	Were incomplete outcome data adequately addressed?	NA
Knowledge of the allocated interventions	Was knowledge of the allocated interventions adequately prevented during the study?	NA
Protection against contamination	Was the study adequately protected against contamination?	Yes
Selective outcome reporting	Was the study free from selective outcome reporting?	Yes
Other risks of bias	Was the study free from other risks of bias?	No *(There was no blinding and there was little information on how data was collected.)*
Overall judgements of risk of bias and directness	Overall risk of bias	High risk of bias *(There were issues with data collection.)*
Overall judgements of risk of bias and directness	Overall directness	Directly applicable

Taylor, 1997

Bibliographic Reference	Taylor, J A; Davis, R L; Kemper, K J; Health care utilization and health status in high-risk children randomized to receive group or individual well child care.; Pediatrics; 1997; vol. 100 (no. 3); e1

Study details

Study type	Randomised controlled trial (RCT)
Study location	USA
Study setting	Community (home visits) and hospital clinic (group health visits)
Study dates	1993 to 1996
Sources of funding	Center for the Future of Children at the David and Lucile Packard Foundation, and the Stuart Foundation.
Inclusion criteria	Individuals with a specified age (range): 0-4 months old. High risk infants/children: Infants were eligible for the project if their mothers had at least one of the following risk factors: single marital status, education level less than completion of high school, participation in Medicaid (as a proxy for poverty), age less than 20 years at delivery, previous substance abuse, or history of abuse as a child.
Exclusion criteria	Individuals that did not speak English. The primary caregiver was not a biologic parent, or an older sibling received primary care from another provider. Child had a serious ongoing medical condition.
Intervention(s)	**Home visits with 1-to-1 education and vaccination:** Study health supervision visits were scheduled at 4, 5, 6, 8, 10, 12, and 15 months of age. At each visit, the study nurse practitioners followed a curriculum of topics to be discussed that was developed before beginning the project. Children randomized to the control arm received traditional one-to-one health supervision visits at home. Immunizations and health screening were provided to all study children regardless of arm.
Comparator	**Hospital clinic group education and vaccination:** Study health supervision visits were scheduled at 4, 5, 6, 8, 10, 12, and 15 months of age. At each visit, the study nurse practitioners followed a curriculum of topics to be discussed that was developed before beginning the project. Patients randomised to the intervention arm were assigned to a cohort of infants with birthdays within 2 months of each other. Group health supervision visits consisted of a discussion of age-appropriate child-rearing issues, led by a nurse practitioner. Each child received a brief physical examination before or after the group session. Immunizations and health screening were provided to all study children regardless of arm.
Outcome measures	Vaccine uptake

Number of participants	210
Duration of follow-up	Follow-up was at 12 months of age
Additional comments	Originally in this study's paper, the group intervention at the heath centre was the 'intervention' and home visiting was the comparator. We have reversed this in the forest plots and tables so there is greater continuity to the other studies in this review with regards to format and to make the data more comparable. A child was considered to be fully immunized if he or she had received three DTP/DT, two OPV/IPV, three hepatitis B, and three Hib vaccines.

Study arms

Group education, vaccination and health screening led by a nurse (N = 106)
Home health supervision, vaccination, and health screening visits by a nurse (N = 104)

Characteristics

Arm-level characteristics

	Hospital clinic group education and vaccination led by a nurse (N = 106)	**Home visits with 1-to-1 education and vaccination by a nurse (N = 104)**
% of mothers aged <20 years *(%)*		
Nominal	22.5	23
% of mothers aged 20 to 30 years *(%)*		
Nominal	60.7	55.4
% of mothers aged 30+ years *(%)*		
Nominal	16.9	19.6

Section	**Question**	**Answer**
Domain 1: Bias arising from the randomisation process	Risk of bias judgement for the randomisation process	Low *(Although the method of randomisation was not provided, the baseline characteristics of the participants was equally balanced between the 2 arms.)*
Domain 2a: Risk of bias due to deviations from the intended	Risk of bias for deviations from the intended interventions	Low

Section	Question	Answer
interventions (effect of assignment to intervention)	(effect of assignment to intervention)	
Domain 2b: Risk of bias due to deviations from the intended interventions (effect of adhering to intervention)	Risk of bias judgement for deviations from the intended interventions (effect of adhering to intervention)	Low
Domain 3. Bias due to missing outcome data	Risk-of-bias judgement for missing outcome data	Low
Domain 4. Bias in measurement of the outcome	Risk-of-bias judgement for measurement of the outcome	Some concerns *(No information was provided as to whether data extraction from the medical records was blinded. Extracting the data would have required effort so there could have been a favourable bias towards the intervention (group) arm.)*
Domain 5. Bias in selection of the reported result	Risk-of-bias judgement for selection of the reported result	Low
Overall bias and Directness	Risk of bias judgement	Some concerns *(Some concerns with data collection)*
	Overall Directness	Directly applicable

Tarca, 2021

Bibliographic Reference	Tarca, Adrian J; Lau, Gloria TY; Mascaro, Filomena; Clifford, Patricia; Campbell, Anita J; Taylor, Ellen; Pre- and post-intervention study examining immunisation rates, documentation, catch-up delivery and the impact of a dedicated immunisation service at a tertiary paediatric hospital; Journal of Paediatrics and Child Health; 2021; vol. 57 (no. 2); 263-267

Study details

Study type	Uncontrolled before-and-after studies
Study location	Australia
Study setting	Hospital wards
Study dates	2017 to 2018
Sources of funding	Not mentioned
Inclusion criteria	Children aged 0 to 18 years
Exclusion criteria	None
Intervention(s)	After: An immunisation nurse reviewed the immunisation record of all inpatient admissions each weekday for a period of 3 months. An immunisation history was

	then obtained from the legal guardian of all children identified as not up-to-date to confirm immunisation status. Only patients identified as not up-to-date had their AIR status confirmed as AIR is unlikely to falsely report a child as up-to-date due to the requirement for manual recording of immunisations at time of administration. This included sighting the electronic school-based immunisation register and if available, a written immunisation record. Immunisations or a catch-up immunisation plan was provided where required.
Comparator	Before: Control (no hospital immunisation service)
Outcome measures	Vaccine uptake
Number of participants	563
Duration of follow-up	3 months
Loss to follow-up	None

Study arms

Immunisation nurse reviewed patients and administered vaccines (N = 291)
Control (no immunisation service in the hospital) (N = 272)

Characteristics

Arm-level characteristics

	Immunisation nurse reviewed patients and administered vaccines (N = 291)	**Control (no immunisation service in the hospital) (N = 272)**
median age (years)		
Nominal	3.2	2.75

Critical appraisal - ACCESS - GUT EPOC risk of bias tool

Section	**Question**	**Answer**
Random sequence generation	Was the allocation sequence adequately generated?	No *(No randomisation)*
Allocation concealment	Was the allocation adequately concealed?	No *(No blinding)*
Baseline outcome measurements	Were baseline outcome measurements similar?	No *(The intervention arm had 89% of participants vaccinated at baseline. The control had 75%.)*
Baseline characteristics	Were baseline characteristics similar?	Partly

Section	Question	Answer
Incomplete outcome data	Were incomplete outcome data adequately addressed?	Yes
Knowledge of the allocated interventions	Was knowledge of the allocated interventions adequately prevented during the study?	No *(No blinding)*
Protection against contamination	Was the study adequately protected against contamination?	Yes
Selective outcome reporting	Was the study free from selective outcome reporting?	Yes
Other risks of bias	Was the study free from other risks of bias?	Yes
Overall judgements of risk of bias and directness	Overall risk of bias	High risk of bias *(No randomisation, no blinding, unequal vaccine uptake at baseline.)*
Overall judgements of risk of bias and directness	Overall directness	Partially applicable *(Vaccines were age-appropriate but the list of vaccines given was not provided.)*

Wilcox, 2001

Bibliographic Reference Wilcox, S A; Koepke, C P; Levenson, R; Thalheimer, J C; Registry-driven, community-based immunization outreach: a randomized controlled trial.; American journal of public health; 2001; vol. 91 (no. 9); 1507-11

Study details

Study type	Randomised controlled trial (RCT)
Study location	USA
Study setting	Community (outreach)
Study dates	1997
Sources of funding	Not provided
Inclusion criteria	A specific age group: Children aged 6 to 10 months old A specified area Children in the Philadelphia Department of Public Health KIDS Immunization Database/Tracking System
Exclusion criteria	None
Intervention(s)	Outreach: Two community-based organizations were contracted by the Department of Public Health to provide outreach to specific neighborhoods. Two thirds of the sample received outreach from a bilingual social services agency and one third from a university nursing center.

	Outreach workers used KIDS registry information to locate the family, obtain the immunisation history, and assess whether the child was up to date. If the child was not up to date, the outreach worker helped the family obtain care and updated the registry. In the case of children who were not up to date, outreach workers made an average of 4 attempts to contact the family or the provider. The 2 community-based organisations followed similar outreach procedures, except that the nursing center placed higher priority on the cases of older children and relied more heavily on home visits. The social services agency was more likely to contact providers directly to obtain immunisation histories. In comparison with the nursing centre, the social services agency had a larger and more experienced staff and had less personnel turnover during the study. Neither facility required outreach workers to hold advanced degrees, but the nursing center looked for outreach workers with previous experience in health care.
Comparator	Control: No intervention. No further information was provided.
Outcome measures	Vaccine uptake
Number of participants	991 (There was no information or data on the further 705 participants who were randomised to the reminders only arm)
Duration of follow-up	The duration of the study's "observation period" was not provided.
Loss to follow-up	None
Additional comments	There were no relevant baseline characteristics for each arm. The vaccines that were administered were: DTP, polio, Hib, HepB. There was randomisation to a third arm that were given reminders. However, no description or outcome data (including uptake) was provided for this arm in the study.

Study arms

Outreach by a social worker or nurse and up to 4 unspecified reminders if required (N = 379)
Control (no intervention) (N = 612)
Mailed reminder letter (N = 705)

Section	Question	Answer
Domain 1: Bias arising from the randomisation process	Risk of bias judgement for the randomisation process	Low *(Although the randomisation method was not provided, the baseline characteristics are equal for both arms.)*
Domain 2a: Risk of bias due to deviations from the intended interventions (effect of assignment to intervention)	Risk of bias for deviations from the intended interventions (effect of assignment to intervention)	Low
Domain 3. Bias due to missing outcome data	Risk-of-bias judgement for missing outcome data	Some concerns *(This study had a third arm with 705 participants but there was no information and no data provided about them.)*

Section	Question	Answer
Domain 4. Bias in measurement of the outcome	Risk-of-bias judgement for measurement of the outcome	High *(Uptake data was provided from parents and providers in the outreach arm and from outreach in the control arm after the study period. Therefore, the method of data collection was different for both arms, there was no assessor blinding, and data collection required effort.)*
Domain 5. Bias in selection of the reported result	Risk-of-bias judgement for selection of the reported result	Low
Overall bias and Directness	Risk of bias judgement	High *(Issues with data collection and missing data from the reminders arm.)*
	Overall Directness	Directly applicable

Wood, 1998

Bibliographic Reference	Wood, D.; Halfon, N.; Donald-Sherbourne, C.; Mazel, R.M.; Schuster, M.; Hamlin, J.S.; Pereyra, M.; Camp, P.; Grabowsky, M.; Duan, N.; Increasing immunization rates among inner-city, African American children: A randomized trial of case management; Journal of the American Medical Association; 1998; vol. 279 (no. 1); 29-34

Study details

Study type	Randomised controlled trial (RCT)
Study location	USA
Study setting	Community (home visits)
Study dates	1994
Sources of funding	Centers of Disease Control and Prevention
Inclusion criteria	A specific age group: Aged 0 to 42 days of life A specified area: Living in 1 of 10 ZIP codes in Los Angeles, which were low income A specified characteristic: African American
Exclusion criteria	Baby died, change of address
Intervention(s)	The case managers conducted in-depth assessments in the home of the child before the infant was 6 weeks of age, with subsequent home visits scheduled 2 weeks prior to when the next immunizations were due. In a family that received all well-child care visits and immunizations on time, home visits would occur when the infants were approximately 3.5 and 5.5 months of age, with a fourth visit being optional. Case managers also followed up by telephone or by home visit after scheduled well-child visits to determine if the family kept the appointment and if the child received the appropriate care. Case managers scheduled more follow-up visits with families that had difficulty in keeping appointments or whose children fell behind in their immunizations. Therefore, the families that were compliant received fewer home visits and had fewer telephone or mail contacts initiated by the case manager. The mean number of home visits was 4.0 (SD 2; range, 0-13), and the mean number of telephone contacts was 7.0 (SD 4.1; range, 0-23). Over the 1 year, the mean number of minutes spent by the case managers in face-to-face contact with a

	family member was 85 minutes (SD 75), and the mean number of minutes on the telephone with a family member was 29.8 (SD 39). The case management intervention included the following components: assessment of client health and other needs, development of a service plan and goals in collaboration with the client, brokering and coordination of services for the client, advocacy with larger institutions and public assistance programs (such as Medicaid), and monitoring and follow-up. At each visit the case manager documented that the client understood the immunization schedule and which immunizations were still remaining, had an appointment with a provider for the next immunization, and was planning on keeping the appointment. The case managers sought to reduce misconceptions regarding false contraindications to vaccination and encouraged clients to be proactive and request immunizations from their providers. Furthermore, the case managers sought to identify and help resolve problems or barriers in the receipt of well-child care, such as lapses in Medicaid insurance or problems with transportation.
Comparator	Control. The control and intervention arm (all participants in this study) were given health passports that were produced by the state of California and contained information on the recommended visits for well-child care and the childhood immunization schedule approved by the CDC. To track the control group the investigators made 1 contact when the infants were aged 4 to 5 months to update the mothers' addresses and telephone numbers.
Outcome measures	Vaccine uptake
Number of participants	367
Duration of follow-up	Approximately 10-12 months
Loss to follow-up	They interviewed 181 (86%) of the 210 control group participants and 186 (89%) of the 209 participants in the case management group, including 29 of 32 who had initially refused to participate in case management. Those that they did not interview were lost to follow-up (29 in the control group and 25 in the intervention group).
Additional information	Being up-to-date at 12 months of age was defined as having received 3 appropriately spaced diphtheria-tetanus-pertussis (DTP) vaccinations, 2 appropriately spaced oral poliovirus (OPV) vaccinations, and 3 appropriately spaced Haemophilus influenzae type B (HIB) vaccinations

Study arms

Outreach case management including reminders (N = 186)	
Control (no intervention) (N = 181)	
Number of participants	419
Duration of follow-up	10 months
Loss to follow-up	Intervention arm: 32 refused case management, 25 were lost to follow-up (N = 25). However, of those who refused case management, 29 were included in the analysis. Control arm: 29 were lost to follow-up.

Characteristics

Arm-level characteristics

	Outreach case management including reminders (N = 186)	Control (no intervention) (N = 181)
Mother's age *(years)*		
Mean/SD	24.7 (6.2)	25.3 (6.2)

Section	Question	Answer
Domain 1: Bias arising from the randomisation process	Risk of bias judgement for the randomisation process	Low
Domain 2a: Risk of bias due to deviations from the intended interventions (effect of assignment to intervention)	Risk of bias for deviations from the intended interventions (effect of assignment to intervention)	Low
Domain 3. Bias due to missing outcome data	Risk-of-bias judgement for missing outcome data	Low
Domain 4. Bias in measurement of the outcome	Risk-of-bias judgement for measurement of the outcome	Some concerns *(Uptake was self-reported by the participants and data collection was not blinded. Therefore, bias could have favoured the intervention arm.)*
Domain 5. Bias in selection of the reported result	Risk-of-bias judgement for selection of the reported result	Low
Overall bias and Directness	Risk of bias judgement	Some concerns *(Some concerns with data collection.)*
	Overall Directness	Directly applicable